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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,506	09/14/2001	Andreas Huth	SCH-1806	5688

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EXAMINER

LIU, HONG

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 12/30/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/831,506

Applicant(s)

HUTH ET AL.

Examiner

Hong Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 12 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

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### **DETAILED ACTION**

Claims 1-9 and 11-15 are pending in this application.

This action is in response to the applicants' amendment and reply filed on November 12, 2002.

#### ***Response to Arguments***

Applicants' arguments filed on November 12, 2002 have been fully considered but they are not persuasive. Rejections to Claims under 35 U.S.C. 112, second paragraph, and 103(a) are maintained.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Election/Restriction***

The amendment claims are still not commensurate with the scope of the elected subject matter. Applicants are expected to cancel the non-elected subject matter.

#### ***Specification***

The amendment to the specification is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The amended specification is not

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considered to be supported by the original disclosure even though applicants state that the amendment has support in the original German PCT text which has not been translated into English. In the absence of a certified English translation of the PCT document, the Examiner cannot verify the original PCT text and the added text is treated as new matter since it differs substantially from the original language in the US filing.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 7 is drawn to a method based on KDR and/or FLT antagonism. This claim is interpreted to include any and all disorders associated with this particular mode of action. The specification reads on any and all psoriasis, eye diseases, diabetic retinopathy, neovascular glaucoma, renal disease, transplant rejection, fibrotic diseases, mesangial-cell-proliferative diseases. However, applicants disclose on P.1 of specification that VEGF "can be " the cause of various diseases resulting from persistent angiogenesis, which implies that there could be causes of these diseases other than VEGF. Additionally, no evidence of in vitro/in vivo effectiveness is seen in the

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specification for one of the (let alone all) of the instant compounds for the uses claimed herein.

See *In re Surrey*, 252 USPQ 724, regarding sufficiency of disclosure. Competent evidence of art-recognized efficacy for intended uses needs to be provided. Any evidence presented must be commensurate in scope with the claims and must clearly demonstrate the likelihood of in vivo use for all uses being claimed. See *Ex parte Powers*, 220 USPQ 925.

Claims 1-9 and 11-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Provisos have been included in the claim (see amended claim 1). The proviso lacks description. Even negative limitations require a description. The MPEP at 2173.05(I) Negative Limitation states “Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983) *aff’d mem.*, 738 F. 2d 453 (Fed. Cir. 1984)” and further, “Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement.” In the instant case, the new concept that has been introduced by the proviso is the specific relationships between  $A$ ,  $R^1$ , and  $R^{2,4,6,7,9}$ . This specific relationship of connectivity was previously not disclosed. This notion that the definition of one variable depends on the definitions of other variables is new. The definition of a variable is no longer independent.

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Rejection to claim 9 under 35 U.S.C. 112, second paragraph, is maintained for the same reason set forth in the previous office action. Intended use is not given material weight. All other rejections are hereby withdrawn in view of applicants' amendment.

***Claim Rejections - 35 USC § 102***

The rejection to claims under 35 U.S.C. 102(b) is hereby withdrawn in view of the provisos in the amended claims.

***Claim Rejections - 35 USC § 103***

Claims 1-6 and 8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ozaki et al. (US Patent 5,716,993) notwithstanding applicants' argument. Claims 1-6 and 8 are compound claims. Although the reference compounds have different utilities, one of ordinary skill in the art, based on the generic teaching of the reference, would nonetheless be motivated to choose any of the alternative substituents to arrive at the instant invention since the species are within the disclosed genus.

For the same reason, claims 1-6 and 8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Schipper et al. (US Patent 3,226,394).

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***Double Patenting***

The rejection to claims 1-12 under the judicially created doctrine of obviousness-type double patenting is hereby withdrawn in view of applicants' insertion of a proviso for R1. This proviso is rejected under 35 U.S.C. 112, first paragraph above.

***Conclusion***

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

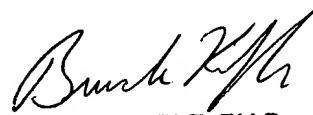
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The

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fax phone number for this group is (703) 308-4734 for “unofficial” purposes and the actual number for **official** business is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

hl  
December 24, 2002



BRUCK KIFLE, PH.D.  
PRIMARY EXAMINER

**Mukund Shah**  
**Supervisory Patent Examiner**  
**Art Unit 1624**